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II.

REMARKS

1. Response to Restriction Requirement

In the Office Action mailed on July 20, 2004, the Examiner has indicated that the application has been restricted under 35 U.S.C. §121 to the following inventions:

- I. Claims 72-80, drawn to compounds; and
- II. Claim 81, drawn to a method of using the compounds of Group I.

In response, Applicants elect, with traverse, Group I, Claims 72-80 drawn to compounds.

In the restriction requirement, the Examiner has restricted the method claims (Group II) from the compound claims (Group 1). However, such a requirement for restriction is improper because it is inconsistent with the Patent Office's stated guidelines that an Examiner must examine the entire application on the merits if a search and examination can be conducted without serious burden.

Specifically, MPEP § 803 states, in part, that "[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP § 803 at 800.4.

In the present case, the Examiner has indicated that the Group (I) (compound claims and a pharmaceutical composition claim) and Group (II) (which claims a method of inhibiting the growth of bacteria in a mammal) are related as "product and process of use." Therefore, a combined search and examination of the method claim and the compound and pharmaceutical composition claims should not impose an undue burden on the Examiner since any pertinent art relating to the compounds and/or pharmaceutical composition is also likely to be relevant to the method using the same pharmaceutical compositions. In fact, one would expect reference to pharmaceutical compositions containing such compounds and methods of using these same compositions in the same documents. In this regard, the Examiner has indicated that "...in the event that Group I is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination provided that the limitations present in the claims (drawn to compounds) are incorporated into the method claims [In re Ochiai 37 USPQ2d 1127]." Accordingly, Applicants submit that such a search and examination of the method claim in combination with compound and pharmaceutical composition claims should not impose a

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serious burden on the Examiner. Therefore, withdrawal of this restriction requirement is respectfully requested.

Further to the restriction requirement, Applicants elect as a disclosed species for prosecution, Compound Number 97, shown in Table II on page 26 of the specification. Compound 97 is a compound of formula II where R^{21} , R^{22} , R^{23} , R^{24} , R^{25} , and n are as defined in Claim 72; R^{15} is $-R^a-Y-R^b-(Z)_x$, specifically $-(CH_2)_3-NH-(CH_2)_9CH_3$, where R^a is $-(CH_2)_3-$, Y is -NH-, R^b is $-(CH_2)_{10}-$, Z is hydrogen and x is 1; R^{16} and R^{25} are methyl; and R^{27} is hydrogen. This compound has the formula:

Pending claims 72-75, 77-78, and 80-81 read on this compound.

2. <u>Information Disclosure Statement - Form PTO/SB/08b</u>

An Information Disclosure Statement (IDS) was mailed by Express Mail to the USPTO on September 15, 2003 for the above-identified patent application. Consideration of the

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documents listed on the form PTO/SB/08b is respectfully requested. Additionally, the Examiner is respectfully requested to return an initialed copy of the form PTO/SB/08b.

In view of the above remarks, reconsideration of the application is respectfully requested.

Respectfully submitted, THERAVANCE, INC.

Date: August 12., 2004_

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